

### **REMARKS**

Applicants have reviewed and considered the Office Action dated December 10, 2007, and the references cited therein. In the Office Action, the Examiner rejected claims 21, 22, 24, 26-29, and 32 under 35 U.S.C. § 102(e) and claims 23, 25, 30 and 31 under 35 U.S.C. § 103(a). In response thereto, claim 21 has been amended. In view of the amendments and the following remarks, Applicants request reconsideration and allowance of the pending claims.

#### **Rejections under 35 U.S.C. § 102(e)**

##### **Independent Claim 21 is Patentable over Shepard**

Claims 21, 22, 24, 26-29, and 32 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Pub. No. 2004/0078078 (Shepard). This rejection is traversed at least for the following reasons.

Claim 21, as amended, is directed to “a spinal bone implant comprising,” in part, “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an instrument.”

Shepard, in contrast, is directed to a two piece allograft cervical fusion block for use in orthopedic surgical procedures, including one component member of load bearing material, such as cortical bone, and another component member made of cancellous bone. *Shepard*, para. [0021]. A dovetailed recess of the cancellous component receives a dovetailed shape projection of the cortical component to hold the two pieces together. *Shepard*, para. [0061]. Bores with pins inserted therethrough are provided to increase stability of the graft, and extend through both the cancellous and cortical components. Shepard explains:

If desired, pins 40 and 42 can be inserted in through going bores 44 and 46 cut through both component members 12 and 30 to increase stability to the graft. The pins 40 and 42 are preferably constructed of cortical bone but can be constructed from any biocompatible material having the necessary strength requirements including metals, plastics compositions and the like and are friction fit in the respective bores 44 and 46. *Shepard*, para. [0063].

In this regard, Shepard discloses bores of varying sizes and configurations which have pins inserted therethrough to stabilize the graft. *Shepard*, para. [0063] – [0069]. However, nowhere does Shepard disclose “a spinal bone implant” having bores which are to remain unfilled, let alone a “spinal bone implant” with a bore “configured to receive an instrument.” That is, Shepard discloses bores only for use in conjunction with stabilizing pins. The bores are specifically provided to limit axial and lateral movement of the two-piece fusion block:

A plurality of bores are cut through the cortical bone member and into the canerous [sic] member to hold pins which are angularly inserted into the bores along opposite sides of the dove tail projection and recess and through the head of the cortical member to limit axial and lateral movement. *Shepard*, para. [0021].

Leaving the bores unfilled, for receipt of an instrument, is not disclosed or suggested by Shepard. Shepard details that the bores receive stabilizing pins to limit axial and lateral movement. Thus, not extending pins through the bores would lead to a less stable implant.

Claim 21, as amended, recites “the bore being configured to receive an instrument.” The Applicants respectfully assert that even were it proper to ignore the specific teaching of Shepard to insert pins through the bores, the bores of Shepard would not be configured to receive an instrument. As noted, an implant manufactured in accordance with Shepard, having bores without pins inserted therethrough, has compromised stability. As discussed at para. [0030] in the present application, the surgeon can use the instrument “to torque and rotate or otherwise reorient the implant to its preferred location.” Were the bores of Shepard to receive an instrument, such as for inserting or repositioning the implant, and were that instrument to be used in the way contemplated, the Shepard implant, already in a state of compromised stability, would be subjected to torque and rotation. The Applicants respectfully assert that this would be contrary to the teachings of Shepard.

Indeed, Shepard specifically discusses ways to reorient the implant:

The cortical front is mated to the cancellous component with the crosspiece inner planar surface being adjacent the cancellous component. The cortical or load bearing component bears not only a compressive load but also serves as an impaction surface. Thus, the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancellous portion of the graft. *Shepard*, para. [0063] (emphasis added).

As is observed from the foregoing, Shepard teaches that a surgeon may orient the bone grafts by tapping the grafts with a suitable instrument, thus eliminating any need for a bore capable of receiving an instrument receiving bore. Such tapping for placement is typical in the art, as discussed at paras. [0026]-[0027] of the present application.

Thus, Shepard teaches inserting stabilizing pins through bores to limit axial and lateral movement. Shepard further teaches that reorientation of the implant may be achieved by tapping on the implant. The Examiner attempts to interpret Shepard in a manner that would provide an implant with bores without stabilizing pins, thus in a compromised state of stability, and insert an instrument through such bores to torque, rotate, or otherwise reorient that implant – notwithstanding Shepard's specific disclosure of manners to reorient the implant that do not torque an implant having compromised stability.

For at least the reasons presented above, Shepard does not disclose “a spinal bone implant” with “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an instrument,” as recited in claim 21. Reconsideration and allowance of claim 21 are thus respectfully requested.

*Claims Depending from Claim 21 are Patentable*

Each of claims 22, 24, 26-29, and 32 depend either directly or indirectly from claim 21. Accordingly, these claims are patentable for at least for the reasons discussed with respect to claim 21 and further in view of their additional recitations. Reconsideration and allowance are thus respectfully requested.

**Rejections under 35 U.S.C. § 103(a)**

**Claim 23 is Not Unpatentable Over Shepard in View of McKay**

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 6,261,586 (McKay). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. McKay does not remedy the disclosure deficiencies of Shepard. McKay teaches a spacer for maintaining a space between adjacent bone in a patient including a load bearing body sized and shaped to fit within the space. *McKay*, col. 10, ll. 40-44. Neither Shepard nor McKay, alone or in combination, disclose, teach, or suggest, “a spinal bone implant” with “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an instrument,” as recited in claim 21. Claim 23 depends directly from claim 21. Accordingly, claim 23 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and allowance of claim 23 are thus respectfully requested.

**Claim 25 is Not Unpatentable Over Shepard in View of Henry**

Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 5,766,252 (Henry). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. Henry does not remedy the disclosure deficiencies of Shepard. Henry teaches an interbody spinal prosthetic implant which includes a rigid member having vertically opposite load-bearing surfaces and sides spaced laterally apart. *Henry*, col. 3, ll. 8-14. Neither Shepard nor Henry, alone or in combination, disclose, teach, or suggest, “a spinal bone implant” with “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-

posterior axis, and the bore being configured to receive an instrument,” as recited in claim 21. Claim 25 depends directly from claim 21. Accordingly, claim 25 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and allowance of claim 25 are thus respectfully requested.

*Claim 30 is Patentable Over Shepard in View of Lahille*

Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 5,554,191 (Lahille). This rejection is traversed at least for the following reasons.

As discussed above, Shepard does not disclose the invention of claim 21. Lahille does not remedy the disclosure deficiencies of Shepard. Lahille teaches an intersomatic cage which includes two parallel branches for insertion into vertebral bodies, a linking portion for linking ends of the branches, and a means for angularly spreading ends of the branches after insertion. *Lahille*, col. 1, ll. 54-61. Neither Shepard nor Lahille, alone or in combination, disclose, teach, or suggest, “a spinal bone implant” with “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an instrument,” as recited in claim 21. Claim 30 depends directly from claim 21. Accordingly, claim 30 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and allowance of claim 30 are thus respectfully requested.

*Claim 31 is Patentable Over Shepard in View of Boyle*

Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Pub. No. 2002/0026242 (Boyle). This rejection is traversed at least for the following reasons.

As mentioned above, Shepard does not disclose the invention of claim 21. Boyle does not remedy the disclosure deficiencies of Shepard. Boyle teaches a ramp-shaped intervertebral implant including a body having an opening extending from upper and lower surfaces thereof. *Boyle*, para. [0038]. Neither Shepard nor Boyle, alone or in combination, disclose, teach, or

suggest “a spinal bone implant” with “a body made of bone . . . the body having a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and posterior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an instrument,” as recited in claim 21. Claim 31 depends directly from claim 21. Accordingly, claim 31 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and allowance are thus respectfully requested.

**CONCLUSION**

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before June 10, 2008, with the required fee for a three-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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Date: 6/10/08

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